(SUV) were compared using linear-mixed modeling at baseline and at four weeks after RT for target and non-target lesions.
Results: Eleven patients were eligible for analysis. There were 13 target lesions (two irradiated target lesions in two patients) and 12 non-target lesions (treated with sorafenib alone). Two patients experienced severe toxicity: one developed hand-foot syndrome and another died during treatment from unrelated causes. There were no severe side effects directly attributable to the combination of RT and sorafenib. The BPI mean 'present' pain scores at baseline, 7 weeks and 12 weeks were 3.9, 1.6, and 1.6 respectively ($p = 0.07$ for 7 weeks vs. baseline; $p = 0.13$ for 12 weeks versus baseline). There was a significant difference in the metabolic response of target lesions versus non-target lesions ($p=0.002$). For target lesions, SUV decreased after RT and sorafenib ($p=0.003$). However, for non-target lesions, there was a trend towards an increase in SUV ($p=0.09$). Only two patients required re-irradiation of a previously treated index lesion. Seven other patients required subsequent RT for symptomatic progression of previously untreated lesions.
Conclusions: The combination RT and sorafenib is feasible and well tolerated as a treatment for palliation of painful bone metastases in patients with metastatic RCC. Both the re-treatment and PET results suggest that RT provides additional palliative benefit in this patient population and should be considered even in those receiving tyrosine-kinase inhibitors like sorafenib.

OC-0050
Linac based SBRT for prostate cancer in 5 fractions: Preliminary report of a Phase II study with FFF delivery
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Purpose/Objective: End point of the present study is to evaluate the technical feasibility and early side effects of a short course hypofractionated high dose LINAC based SBRT delivered with Flattened Filter Free (FFF) beams, and SpaceOAR as a spacer between rectum and prostate.
Materials and Methods: This is a prospective phase-I-II pilot feasibility study, started on February 2012. Inclusion criteria were: age ≤ 80 years, WHO PS ≤ 2, PSA ≤ 20 ng/ml, histologically proven prostate adenocarcinoma(risk of microscopic nodal involvement ≤ 15%), T1-T2 stage, no distant metastases, no previous prostate surgery other than TURP, no malignant tumours in the previous 5 years, IPSS 0-7. The schedule was 5 x 7 Gy = 35 Gy, delivered in 5 alternative days (NTD2 between 70 and 85 Gy for an α/ß between 3 and 1.5 Gy, respectively). SBRT was delivered using the volumetric modulated arc technique by RapidArc, with photon beam energy of 10 MV FFF (Filter Flattening Free) and maximum dose rate of 2400 MU/min. Physical examinations and toxicity assessments were performed during and after SBRT according to CTCAE v4.0 toxicity scale. EPIC questionnaires were used for Quality of Life assessing. Tumour response was evaluated on ASTRO PHOENIX definition (+2 from Nadir of PSA). Neo-adjuvant/concomitant hormonal therapy was prescribed based on the risk according to NCCN classification. SpaceOAR was implanted by intraperineal injection as a spacer to enlarge the minimum distance between prostate and anterior rectal wall. The SpaceOAR implant was optional and based on clinician decision for each case.
Results: With a median follow-up of 6 months(1-9),40 patients were treated with this schedule and were evaluable for the current analysis. 34/40 patients were officially recruited in the protocol and met perfectly all inclusion criteria. Other 6/40 'out of trial' were treated with the same protocol. In the trial, according to NCCN criteria, 21/34 patients were low-risk and 12/34 were Intermediate risk. Median Age was 69.6(56-80), median initial PSA was 6.33 ng/ml(range:0.50-12 ng/ml). Median Gleason score was 6.33(6-7). Median treatment duration was 11.8 days(9-22). All patients completed the treatment as programmed. Acute Toxicities were as follow: Rectum G0 in 21/34 cases(62%), G1 in 11/34(33%); G2 in 2/34(5%). Genito-urinary G0 in 15/34 cases(45%), G1 in 7/34(20%), G2 in 12/34(35%). In two G2 urinary retention cases, the placement of intermittent catheter was needed(in both cases prostate dimension was superior than100cc). No acute G3-5 was found in the trial and 'out of trial'patients. Median treatment time was 109 seconds(63-124). SpaceOAR was implanted in 9 patients with a single case of rectal fascia infection resolved with antibiotics. During Follow-up, PSA reduction was documented in all treated patients.
Conclusions: Our early findings suggest that LINAC based SBRT FFF treatment for prostate cancer in 5 fractions is feasible, fast and well tolerated in acute setting for the first 40 treated patients. Longer follow-up is needed for definitive assessment of late toxicity and clinical outcome.

OC-0051
GU outcomes & toxicity 5 years after protons for low- & intermediate-risk prostate cancer: Two prospective trials
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Purpose/Objective: To assess urinary (GU) function and toxicity in patients treated with image-guided proton therapy (PT) for early- and intermediate-risk prostate cancer and to analyze the impact of pretreatment urinary obstructive symptoms on urinary function after PT.
Materials and Methods: Two prospective trials accrued 171 prostate cancer patients from August 2006 to September 2007. Low-risk patients received 78 cobalt gray equivalent (CGE) in 39 fractions and intermediate-risk patients received 78 to 82 CGE. Median follow-up was 5 years. The International Prostate Symptom Score (IPSS) and GU toxicities (per CTCAE v3.0 and v4.0) were documented prospectively.
Results: Five transient GU events were scored Gr 3 per CTCAE v4.0, for a cumulative late GU toxicity rate of 2.9% at 5 years. There were no Gr 4 or 5 events. On multivariate analysis (MVA), the only factor predictive of Gr 2+ GU toxicity was pretreatment GU symptom management ($p=0.0058$).
Patients with pretreatment IPSS of 15-25 had a decline (clinical improvement) in median IPSS from 18 before treatment to 10 at their 60-month follow-up. At last follow-up,18 (54.5%) patients had a ≥ 5-point decline, 14 (42.5%) remained stable, and 2 patients (3%) had a ≥ 5-point rise (deterioration) in IPSS. Patients with IPSS <15 had a stable median IPSS of 6 before treatment and at 60 months.
Conclusions: Urologic toxicity at 5 years with image-guided PT has been uncommon and transient. Patients with pretreatment IPSS of < 15 had stable urinary function 5 years after PT, but patients with 15-25 showed substantial improvement (decline) in median IPSS, a finding not explained by initiation or dose adjustment of alpha blockers. This suggests that PT provides a minimally toxic and effective treatment for low and intermediate prostate cancer patients, including those with significant pretreatment GU dysfunction (IPSS15-25).

OC-0052
Late toxicity in the randomized phase III Dutch Hypofractionation Trial for prostate cancer patients (HYPRO).
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Purpose/Objective: Accumulating evidence demonstrates the sensitivity of prostate cancer to fractionation, estimating a low α/ß ratio. This suggests a significant therapeutic benefit of hypofractionation, delivering a higher biological dose to the prostate without increasing toxicity. To test this hypothesis a randomized multicenter phase III Hypofractionation Trial was performed in The Netherland. Here we report on the first results of late toxicity.
Materials and Methods: Between April 2007 and January 2011, 820 men with localized prostate cancer were included. They were randomly assigned to a standard fractionation (SF) arm of 39x2 Gy (5 fractions a week), or a hypofractionated (HF) arm of 19x3.4 Gy (3 fractions a week). Primary endpoints were relapse-free survival (RFS) and toxicity scores. The late toxicity scores were measured twice a year after finishing the radiation course (RC) using RTOG/EORTC criteria. The highest grade scored in the follow-up was considered. Analyses were done based on the intention to treat.
Results: To each fractionation arm 410 patients were randomly assigned. The median follow-up was 27 months (range 2.3-57 months). A grade ≥ 2 late gastrointestinal toxicity (GI) after finishing the RC was reported by 15% of the patients treated with SF and by 20% of the